diamondback 360°

ORBITAL ATHERECTOMY SYSTEM

Controller Manual Part I

Instructions for Use

Model DB-2000

CSI®

© 2009 Cardiovascular Systems, Inc.

Introduction

This document describes the components and use of the Diamondback 360º® Orbital Atherectomy Controller (Controller). The Controller is a component of the Diamondback Orbital Atherectomy System (OAS). Read this document thoroughly before using the OAS, Controller, or any other components. Review the contraindications, restrictions, warnings, and precautions carefully. Additional instructions and information are found in the Diamondback Orbital Atherectomy Device (OAD) Instructions for Use and package inserts included with separately packaged components. Read all instructions completely before using the OAS or any components.

Indications for Use

The Diamondback Orbital Atherectomy System is a percutaneous orbital atherectomy system indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and who are acceptable candidates for percutaneous transluminal atherectomy.
The OAS is also indicated for removal of stenotic material from artificial arteriovenous dialysis fistulae (AV shunt).

Diamondback 360 Orbital Atherectomy System (OAS) Description

CSI Supplied Equipment

- Orbital Atherectomy Device (OAD)
- Controller
- Guide Wire - as specified in the OAD Instructions for Use
- Gas input line and connector – connects from the controller to the air supply

Additional Components

These are independently obtained, as listed below. Follow the original manufacturer's instructions for each independently sourced component.

- Guide Catheter / Sheath Introducer – See the appropriate Instructions for Use for recommended guide catheter sheath introducer sizes.
- Compressed Gas Cylinder or house air supply – The gas must be air or nitrogen.
- Cylinder Pressure Regulator – The regulator must be capable of delivering at least 5 scfm (140 liter/min) at 85-100 psi (5.8-6.9 bar).
- Normal Saline Solution for Injection – At least one full 1-liter bag must be available.
- Other equipment as needed for interventional procedures.

Diamondback 360 Orbital Atherectomy Controller

This document explains the function of the Orbital Atherectomy Controller (Controller). Device specific instructions for use are available separately as packaged with the Orbital Atherectomy Device (OAD).

The Orbital Atherectomy Controller (Controller) is an electro-mechanical control system. The functions of the Controller include:

- Regulation of gas pressure to the turbine that controls Shaft/Crown rotational speed..
- Recording of operation time including event time, and total time.
- Regulation of saline flow through the Sheath covering the Shaft.

Contraindications, Restrictions, Warnings and Precautions

Contraindications

Refer to the OAD Instructions for Use for the associated contraindications.

Restrictions

- The OAS should only be used by physicians who are experienced in peripheral angioplasty at his or her institution and trained on the use of the OAS.
- **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Warnings

- If mechanical failure of the Controller occurs before or during the atherectomy procedure, discontinue use immediately and return the product to Cardiovascular Systems, Inc. Do not attempt to use a damaged OAD, Controller, or other system component. Use of damaged components may result in system malfunction or patient injury.

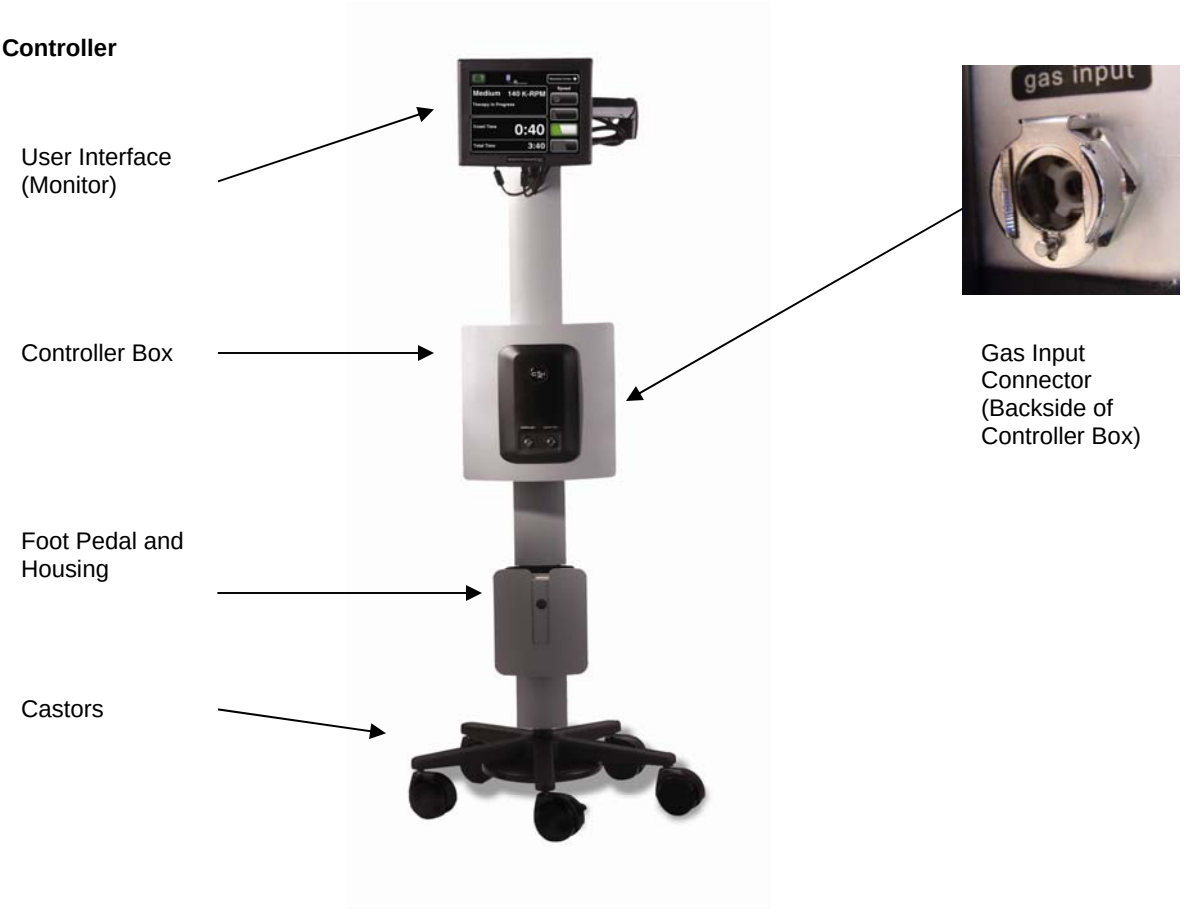
© 2009 Cardiovascular Systems, Inc.

- Never connect the Controller to an oxygen cylinder or use oxygen as the compressed gas for the system. Use of oxygen may result in an explosion. Only use compressed air or nitrogen.
- Do not operate the Controller with gas pressures in excess of 100 psi (6.9 bar). If a hissing noise is noted from the Controller, check to make sure that the gas pressure supplied to the Controller (located at the rear of the controller) is properly attached via the gas line connector and the supply pressure does not exceed 100 psi (6.9 bar). The Controller is equipped with a pressure relief valve to protect against excessive inlet pressure.
- Never operate in the presence of flammable gas.
- Do not remove controller cover due to electrical shock hazard. Refer servicing to qualified personnel.

Precautions

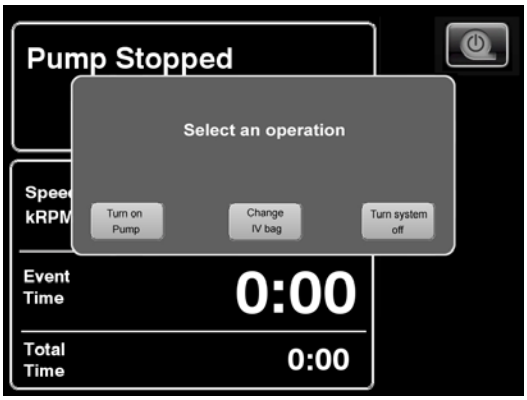
- Do not place items on the controller box, spill saline or other fluids on the Controller. Saline or fluids inside the Controller may result in corrosion or electrical hazard.
- Make sure the cylinder pressure regulator's fitting is compatible with the gas cylinder used.
- Verify the type of gas coupling provided with the Controller prior to procuring a pressure regulator and connecting hose. If necessary, use suitable adapters to make the connection.
- Do not connect anything to the monitor connections other than the intended components.
- The controller should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Controller and Orbital Atherectomy System should be observed to verify normal operation
- The Controller is only to be used with the supplied foot pedal. Use of other non-Cardiovascular Systems, Inc supplied foot pedals may result in increased emissions or decreased immunity of the orbital atherectomy system.

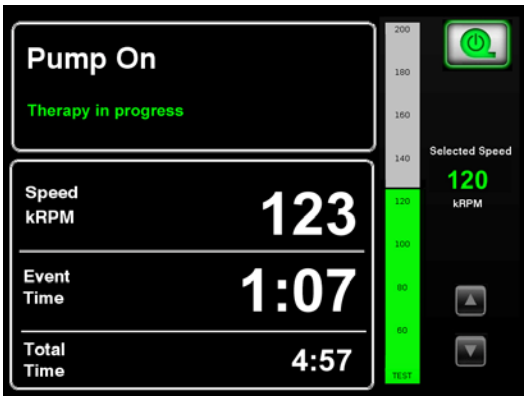
Controller



© 2009 Cardiovascular Systems, Inc.

User Interface





The touch screen display of the Controller displays the following:

Operation Window
The operations window allows user to Turn the pump on, Change IV Bag and Turn the system off
Upon selecting "Turn the pump on" display of the Controller displays the following:

User Controls Area:
Contains controls that allow user to do the following:
Pump On/Off button
Speed gauge and speed selection control
Speed increment/decrement controls
Speed set point display

System Status Area:
Feedback about the system status is displayed in this area. Includes state and notification information and user prompts.
System / Notification Status
Indicate system status information. A notification condition describes the active notification.
System / Notification Prompt
System prompt shows the prompt text for action required by the system status.
Notification prompt tells the operator what can be done from a user perspective about an active notification condition.

Therapy Status Area:
The Therapy Status Area displays the following therapy information:
Speed is the actual speed of the OAD in thousands of RPM
Event time is the elapsed time between therapy (OAD) start and stop for the last therapy session. When the turbine is started for the next session the event time is reset to zero.
Total time is the summation of all event times. This value is only zero after power up.

Controller Front Panel
Turbine Gas Connect – The Turbine Gas Hose of the OAD connects to the Turbine Gas Connection on the front of the controller by pushing in until it locks in place. It can be released by pressing down on the release connection on the controller fitting

Optical Tachometer Fiber Connect – The Optical Tachometer Fiber connects to the Optical Tachometer Fiber connector on the front of the controller by pushing in until it locks in place. It can be released by pressing down on the release connection on the controller fitting
The Optical Tachometer Fiber carries light from the Control Handle to the Controller to measure Shaft/Crown rotational speed.

© 2009 Cardiovascular Systems, Inc.

Controller Front Panel

Controller Back Panel

Controller Back Panel

Power On/Off Switch – The power switch is used to turn the Controller On and Off. The power down sequence is to turn off the user interface first via the touchscreen and then hard power down via controller switch.

Power Input – The power cord plugs into the Controller and a conventional 100-240 VAC receptacle, 1A at 50-60 Hz(as indicated on the label located on the back of the Controller) and provides power to the Controller. Fuse rating is 250 V, 4A Slow Blow, Type T

Gas Input – Standard, hospital supplied tubing connects the regulator of the compressed gas cylinder to the Controller allowing for gas to be supplied to the Turbine.

Potential equalization terminal - For the purpose of testing the grounding of the controller. Note: remainder of roll stand may not be grounded.

Controller Side Panel

Roller Pump – Pumps saline from the 1000 ml saline bag through the Sheath and around the Shaft.

Foot Pedal

Foot Pedal Housing – The basket below the Controller houses the Foot Pedal and power cord for storage

Foot Pedal

The Foot Pedal comes pre-connected to the Controller. When the pump is on and a speed setting selected, depressing the electrical Foot Pedal once causes saline to flow at the high pump speed. Depressing the Foot Pedal again (within five seconds) opens the compressed gas line and starts the turbine, which results in Shaft/Crown rotation. Releasing the Foot Pedal closes the compressed gas line and stops Shaft/Crown rotation. The pump speed automatically resets to low pump speed within 7 seconds after release of the foot pedal.

Compressed Gas Cylinder and Regulator

Additional equipment needed to operate the OAS includes a compressed gas cylinder and cylinder pressure regulator or a hard plumbed compressed air line set between 85-100 psi.

Compresses Gas System

A compressed gas system must contain air or nitrogen. A cylinder capacity of at least 80 standard cubic feet (2250 liter) is recommended and will provide approximately 20 minutes of service with the OAS running at full speed. Larger cylinders may be used. A fully charged spare cylinder should always be available.

Cylinder pressure regulator – The cylinder pressure regulator must be capable of delivering at least 5 scfm (140 liter/min) at 85-100 psi (5.8-6.9 bar). A relieving type cylinder pressure regulator is preferred. The regulator's cylinder filling capability should be compatible with the gas cylinder being used.

Hospital Air System

A hospital compressed air or nitrogen system can be used in place of a gas cylinder and regulator.

1. The compressed gas must be air or nitrogen.
2. The gas must be clean, dry, and oil free.
3. The gas pressure must be 80-100 psi (5.8-6.9 bar, 551.6-689.6 kPa) at the inlet to the Controller.
4. The system must be capable of supplying gas at a rate of 5 scfm (140 liter/min).

© 2009 Cardiovascular Systems, Inc.

OAS Assembly and Setup

Pre-Procedure Equipment Setup
Ensure all components are available for system set up.

Note: Hang a full 1-liter bag of saline from the pole on the Controller.

Note: Verify the saline tubing is not kinked or damaged and that the tubing is properly inserted into the roller pump.

Follow the directions below to set up the OAS.
Controller Setup
1. Verify the power cord is connected to the back of the Controller.
2. Insert the other end of the power cord into a properly rated, hospital grade receptacle.

Compressed Gas Cylinder Setup
1. Setup the compressed gas (air or nitrogen), regulator, and tubing according to standard hospital protocol.
2. Connect the gas tubing to the Gas Input connector on the back of the Controller.

Note: Push down on the Release Button to open the connector before inserting the hose connector. Carefully connect the hose to prevent damage to the connector O-ring. Damage to the O-ring (and "hissing") can occur if the connector is plugged into the controller when the mating connector is closed.

OPEN

CLOSED

© 2009 Cardiovascular Systems, Inc.

Orbital Atherectomy Device (OAD) Setup

Refer to the OAD Instructions for Use for complete instructions related to OAD setup.

Connecting the OAD to the Controller:

1. Remove the tubing from the OAD package and pass it out of the sterile field to the circulator or non-sterile personnel.

2. Have the circulator or non-sterile personnel connect the Turbine Gas Intake Hose to the Controller at the Turbine Gas connector on the front of the Controller.

3. Have the circulator or non-sterile personnel connect the Optical Tachometer Fiber to the Controller at the Optical Tachometer Fiber connector on the front of the Controller.

   Note: Care should be taken to keep the Fiber end clean and free of any material that could interfere with optical transmissions.

4. The circulator or non-sterile personnel performs the following steps:
   a. Ensure the Controller On/Off switch is in the off position.
   b. Hang a full 1-liter bag of saline from the pole on the Controller.
   c. Connect the saline tubing to the saline bag using standard hospital procedure.
   d. Lift the roller pump lever to open the roller pump door.
   e. Place the saline tubing into the grooved tubing guides of the roller pump. Ensure that the tubing guide located on top of the pump housing is appropriately adjusted for tubing diameter. See figure A.
   f. Close the roller pump door. See Figure B.

Figure A

Figure B

5. Turn the Control Unit on by pressing the Power On/Off switch on the back of the Controller.
6. Turn on the Pump by touching the Turn Pump On button in the operation window.
   a. Note: Controller will default to Test Mode (60kRPM) once pump has been turned on.
7. Purge air from the saline tubing:
   a. Press the Foot Pedal to start saline flow at high pump speed.
   b. Watch for saline to exit from the saline tubing and ensure there are no air bubbles present in the saline tubing.
   c. When all the air is purged from the saline tubing, connect the saline line to the OAD saline connection and repeat steps a through c to purge air from the OAD sheath.

8. Test the system to confirm device operation by depressing the foot pedal to begin spinning the Crown. Hold the guide wire firmly during the test. When test mode is complete, an operational device is ready to be inserted into the introducer in the patient.

© 2009 Cardiovascular Systems, Inc.

Procedure
Refer to OAD Instructions for Use for procedural information.

Saline Bag Change
When the Saline Low notification appears it is time to change the saline bag.

1. Stop the pump by touching the pump On/Off button.
2. Touch the Change IV Bag Button
3. Remove the bag spike from the bag and hold it for reuse.
4. Remove the empty bag from the pole.
5. Place a new bag on the pole and insert the bag spike.
6. Touch the OK button in the operation window to reset the saline volume to full.
    a. If saline bag has not been changed touch Cancel in the operation window
7. Restart the pump by touching the Turn Pump On button in the operation window.

Device Change
To change out a device:

1. Stop the pump by touching the pump On/Off button.
2. Disconnect the tubing from the device handle in use.
3. Attach the tubing to the new device.
4. Touch the Turn Pump On button in the operation window to start the pump to prime saline through the device. Stepping on the foot pedal will increase the flow rate to high for faster priming
    a. Note: Controller will default to Test Mode (60kRPM) once pump has been turned on.
5. Refer to OAD Instructions for Use for procedural information.

Turning Off the Controller

1. Stop the pump by touching the pump On/Off button.
2. Touch the Turn System Off button in the operation window
3. Touch OK to shut down system
4. When the CSI splash screen is seen turn off the main power to the controller by pressing the On/Off button on the back of the controller.

Cleaning the Controller and Foot Pedal
The Controller System should be cleaned regularly with a soft cloth dampened in water and mild detergent. Isopropyl alcohol/ water mix (70/30) or Cydex should be used to clean and disinfect the Controller System from blood or other contaminants. Do not immerse the Controller, Monitor or Foot Pedal in fluid. Avoid use of solvents or abrasive cleaners, which may damage the Controller System components.

Controller Maintenance and Calibration
The Controller does not require routine or periodic maintenance or calibration. Contact CSI if questions arise related to Controller function or performance.

Controller Repair and Shipping
Contact CSI if Controller repairs are required or for shipping instructions.

Classifications, per IEC/UL/CSA/EN 60601-1

- Class I Equipment
- Type CF Applied Part
- Degree of protection against the ingress of water: IPX1 (Controller), IPX0 (Monitor), IPX8 (Footswitch)
- Equipment not suitable for use in the presence of flammable anesthetics
- Operation Mode: Continuous

Storage,Transport, and Operating Conditions
Storage and Transport: -50°C to +60°C (-58°F to 140°F), 10% to 100% Relative Humidity, 5000 to 1060 hPA
Operating: 10 to 40° C (50 to 104° F)

Electromagnetic Compliance
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

a. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. This Product is intended for use in the electromagnetic environments specified.
b. The end user of this product should assure it is used in such an environment.
    i. Portable and mobile RF Communications equipment should not be used at close distances.
    ii. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

© 2009 Cardiovascular Systems, Inc.

Controller Messages

STATUS MESSAGE	ACTION MESSAGE	MEANING WHEN DISPLAYED	USER ACTION
PUMP OFF	START PUMP	Pump is off with no notifications	Start pump
PUMP ON	SET SPEED	Pump is on, no speed selected	Select speed
LOW SPEED	NONE	Low speed selected	N/A
MEDIUM SPEED	NONE	Medium speed selected	N/A
HIGH SPEED	NONE	High speed selected	N/A
SPEED OUT OF RANGE	CALL SERVICE	Speed is detected, when stop has been requested	Return controller for service
PUMP FAILURE	CALL SERVICE	DEFECTIVE PUMP	Return controller for service
PRESSURE OUT OF RANGE	CALL SERVICE	Pressure is detected, when stop has been requested	Return controller for service
FLUID SUPPLY EMPTY	FLUID SUPPLY EMPTY	Controller has calculated that the saline bag is empty	Change saline bag and reset
MAX PRESSURE EXCEEDED	MAX PRESSURE EXCEEDED	The controller has detected that output pressure exceeded maximum for > 10 seconds	Reselect lower speed or exchange device
MAX SPEED EXCEEDED	MAX SPEED EXCEEDED	The controller has detected that output speed exceeded maximum for > 10 seconds	Reselect lower speed or exchange device
NO SPEED DETECTED	CHECK AND RETRY	No Tachometer reading detected	1. Check fiber optic connections 2. Replace fiber optic
SYSTEM FAILURE	CALL SERVICE	Controller Failure	Return controller for service
PUMP STOPPED	CLOSE DOOR	Saline pump is open	Close pump
NO SPEED DETECTED	CHECK AND RETRY	Speed test failed	1. Check device connections 2. Replace device
SALINE LOW	CHECK BAG	Controller has calculated a low saline supply	Check saline level and change bag. Reset level when needed.
EVENT TIME EXCEEDED	NONE	Event Time has exceeded 90 seconds	Follow event times listed in OAD IFU
APPROACHING MAX EVENT TIME	NONE	Event Time is approaching 90 seconds	Follow event times listed in OAD IFU
FLOW OUT OF RANGE	NONE	Controller has detected improper saline flow rate condition.	Call for Assistance

.

© 2009 Cardiovascular Systems, Inc.

Appendix A – Symbols

Attention, Consult Accompanying Documents

On

Off

Equal Potential Terminal

Protective Earth

Electrical Safety Rating (Type CF Applied Part, IPX1)

Fuse

Manufacturer

3MSP

MEDICAL EQUIPMENT

WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1,
IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1

© 2009 Cardiovascular Systems, Inc.

Appendix B – DISCLAIMER OF WARRANTY

DISCLAIMER OF WARRANTY

Cardiovascular Systems, Inc. warrants that reasonable care has been used in the manufacture of this device. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER EXPRESSED OR IMPLIED, WRITTEN OR ORAL, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE. AS A RESULT OF BIOLOGICAL DIFFERENCES IN INDIVIDUALS, NO PRODUCT IS 100 PERCENT EFFECTIVE UNDER ALL CIRCUMSTANCES. BECAUSE OF THIS FACT, AND SINCE CARDIOVASCULAR SYSTEMS, INC. HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS DEVICE IS USED, DIAGNOSIS OF THE PATIENT, METHODS OF ADMINISTRATION OR ITS HANDLING AFTER THE DEVICE LEAVES OUR POSSESSION, CARDIOVASCULAR SYSTEMS, INC. DOES NOT WARRANT EITHER FOR A GOOD EFFECT OR AGAINST ALL ILL EFFECT FOLLOWING ITS USE.

CARDIOVASCULAR SYSTEMS, INC. (INCLUDING ITS AFFILIATED ENTITIES, OWNERS, DIRECTORS, OFFICERS, EMPLOYEES, AGENTS AND VENDORS) SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING FROM OR RELATED TO THE USE OF THIS DEVICE.

No person has authority to bind Cardiovascular Systems, Inc. to any representation, warranty, or liability except as set forth in this Disclaimer of Warranty.

Cardiovascular Systems, Inc. may, at its sole discretion, replace any device that is determined to have been defective at the time of shipment.

The exclusions, disclaimers, and limitations set forth in this Disclaimer of Warranty are not intended to, and shall not be construed as to, contravene mandatory provisions of any applicable law or regulation. If any part of this Disclaimer of Warranty is held to be illegal or unenforceable by a court of competent jurisdiction, the part shall be modified so as to be enforceable to the maximum extent possible. If the part cannot be modified, then that part may be severed and the other parts of this Disclaimer of Warranty shall remain in full force and effect.

Diamondback 360º and CSI are registered trademarks of Cardiovascular Systems, Inc

Cardiovascular Systems, Inc.
St. Paul, Minnesota 55112 USA
Telephone: 651.259.1600

© 2009 Cardiovascular Systems, Inc.

diamondback 360°
ORBITAL ATHERECTOMY SYSTEM

Controller Manual Part II
Service and Maintenance

Model DB-2000

CSI®

© 2009 Cardiovascular Systems, Inc.

Cleaning the Controller and Foot Pedal
The Controller System should be cleaned regularly with a soft cloth dampened in water and mild detergent. Isopropyl alcohol/ water mix (70/30) or Cydex should be used to clean and disinfect the Controller System from blood or other contaminants. Do not immerse the Controller, Monitor or Foot Pedal in fluid. Avoid use of solvents or abrasive cleaners, which may damage the Controller System components.

Controller Maintenance and Calibration
The Controller does not require routine or periodic maintenance or calibration. Contact CSI if questions arise related to Controller function or performance.

Controller Repair and Shipping
Contact CSI if Controller repairs are required or for shipping instructions.

Classifications, per IEC/UL/CSA/EN 60601-1
- Class I Equipment
- Type CF Applied Part
- Degree of protection against the ingress of water: IPX1 (Controller), IPX0 (Monitor), IPX8 (Footswitch)
- Equipment not suitable for use in the presence of flammable anesthetics
- Operation Mode: Continuous

Storage, Transport, and Operating Conditions
Storage and Transport: -50°C to +60°C (-58°F to 140°F), 10% to 100% Relative Humidity, 5000 to 1060 hPA
Operating: 10 to 40° C (50 to 104° F)

Electromagnetic Compliance
Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

A. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. This Product is intended for use in the electromagnetic environments specified.
B. The end user of this product should assure it is used in such an environment.
   i. Portable and mobile RF Communications equipment should not be used at close distances.
   ii. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

© 2009 Cardiovascular Systems, Inc.

Controller Messages

STATUS MESSAGE	ACTION MESSAGE	MEANING WHEN DISPLAYED	USER ACTION
PUMP OFF	START PUMP	Pump is off with no notifications	Start pump
PUMP ON	SET SPEED	Pump is on, no speed selected	Select speed
LOW SPEED	NONE	Low speed selected	N/A
MEDIUM SPEED	NONE	Medium speed selected	N/A
HIGH SPEED	NONE	High speed selected	N/A
SPEED OUT OF RANGE	CALL SERVICE	Speed is detected, when stop has been requested	Return controller for service
PUMP FAILURE	CALL SERVICE	DEFECTIVE PUMP	Return controller for service
PRESSURE OUT OF RANGE	CALL SERVICE	Pressure is detected, when stop has been requested	Return controller for service
FLUID SUPPLY EMPTY	FLUID SUPPLY EMPTY	Controller has calculated that the saline bag is empty	Change saline bag and reset
MAX PRESSURE EXCEEDED	MAX PRESSURE EXCEEDED	The controller has detected that output pressure exceeded maximum for > 10 seconds	Reselect lower speed or exchange device
MAX SPEED EXCEEDED	MAX SPEED EXCEEDED	The controller has detected that output speed exceeded maximum for > 10 seconds	Reselect lower speed or exchange device
NO SPEED DETECTED	CHECK AND RETRY	No Tachometer reading detected	1. Check fiber optic connections 2. Replace fiber optic
SYSTEM FAILURE	CALL SERVICE	Controller Failure	Return controller for service
PUMP STOPPED	CLOSE DOOR	Saline pump is open	Close pump
NO SPEED DETECTED	CHECK AND RETRY	Speed test failed	1. Check device connections 2. Replace device
SALINE LOW	CHECK BAG	Controller has calculated a low saline supply	Check saline level and change bag. Reset level when needed.
EVENT TIME EXCEEDED	NONE	Event Time has exceeded 90 seconds	Follow event times listed in OAD IFU
APPROACHING MAX EVENT TIME	NONE	Event Time is approaching 90 seconds	Follow event times listed in OAD IFU
FLOW OUT OF RANGE	NONE	Controller has detected improper saline flow rate condition.	Call for Assistance

© 2009 Cardiovascular Systems, Inc.

Appendix A – Symbols

Attention, Consult Accompanying Documents

 On

Off

Equal Potential Terminal

Protective Earth

Electrical Safety Rating (Type CF Applied Part, IPX1)

Fuse

Manufacturer

3MSP

MEDICAL EQUIPMENT

WITH RESPECT TO ELECTRIC SHOCK,
FIRE AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1,
IEC/EN 60601-1, CAN/CSA C22.2 No. 601.1

© 2009 Cardiovascular Systems, Inc.

Appendix B – DISCLAIMER OF WARRANTY

DISCLAIMER OF WARRANTY

Cardiovascular Systems, Inc. warrants that reasonable care has been used in the manufacture of this device. THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES WHETHER EXPRESSED OR IMPLIED, WRITTEN OR ORAL, INCLUDING BUT NOT LIMITED TO ANY WARRANTIES OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE. AS A RESULT OF BIOLOGICAL DIFFERENCES IN INDIVIDUALS, NO PRODUCT IS 100 PERCENT EFFECTIVE UNDER ALL CIRCUMSTANCES. BECAUSE OF THIS FACT, AND SINCE CARDIOVASCULAR SYSTEMS, INC. HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH THIS DEVICE IS USED, DIAGNOSIS OF THE PATIENT, METHODS OF ADMINISTRATION OR ITS HANDLING AFTER THE DEVICE LEAVES OUR POSSESSION, CARDIOVASCULAR SYSTEMS, INC. DOES NOT WARRANT EITHER FOR A GOOD EFFECT OR AGAINST ALL ILL EFFECT FOLLOWING ITS USE.

CARDIOVASCULAR SYSTEMS, INC. (INCLUDING ITS AFFILIATED ENTITIES, OWNERS, DIRECTORS, OFFICERS, EMPLOYEES, AGENTS AND VENDORS) SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE ARISING FROM OR RELATED TO THE USE OF THIS DEVICE.

No person has authority to bind Cardiovascular Systems, Inc. to any representation, warranty, or liability except as set forth in this Disclaimer of Warranty.

Cardiovascular Systems, Inc. may, at its sole discretion, replace any device that is determined to have been defective at the time of shipment.

The exclusions, disclaimers, and limitations set forth in this Disclaimer of Warranty are not intended to, and shall not be construed as to, contravene mandatory provisions of any applicable law or regulation. If any part of this Disclaimer of Warranty is held to be illegal or unenforceable by a court of competent jurisdiction, the part shall be modified so as to be enforceable to the maximum extent possible. If the part cannot be modified, then that part may be severed and the other parts of this Disclaimer of Warranty shall remain in full force and effect.

Diamondback 360º and CSI are registered trademarks of Cardiovascular Systems, Inc

Cardiovascular Systems, Inc.
St. Paul, Minnesota 55112 USA
Telephone: 651.259.1600

© 2009 Cardiovascular Systems, Inc.

Appendix C – MAINTENANCE AND CALIBRATION STATEMENT

Diamondback 360 Model DB-2000 Controller Maintenance & Calibration Statement

13 May, 2008

As outlined in Cardiovascular Systems, Inc. Instructions for Use (IFU) supplied with each unit, the Diamondback 360 DB-2000 controller does not require routine periodic maintenance or calibration.

For Questions, Please Contact:

Director of Quality Assurance
Cardiovascular Systems, Inc.
St. Paul, Minnesota 55112 USA
Telephone: 651.259.1600

© 2009 Cardiovascular Systems, Inc.